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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,389	09/04/2001	Paul James Davis	IMIN.P-002-2	9864

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/944,389

Applicant(s)

DAVIS ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-102 is/are pending in the application.
- 4a) Of the above claim(s) 87,88 and 96-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-86 and 89-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____                                     |

### DETAILED ACTION

1. Applicant's request for reconsideration filed 9/22/03 has been received. Claims 26-102 are pending. Claims 87, 88 and 96-102 have been withdrawn from consideration as being drawn to an independent invention. Applicant argues that these claims are generic because even though they do not require the presence of the housing, they also do not preclude its presence. This argument has been fully considered but is not deemed persuasive. The device of claims 87, 88 and 96-102 are different from those of claim 26, for example, because it does not have the same parts and are so divergent that it is classified in a different class (422) and subclass (58).
2. The text of those US codes not found in this office action may be found in a previous office action.
3. All rejections not reiterated herein below are withdrawn.

### *Claim Rejections - 35 USC § 103*

4. Claims 26, 27, 29-30, 32-36, 39-46, 48, 49, 51-55, 58-63, 84-86, 89, 91-93 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisinger et al (US 4,943,522).

Eisinger discloses an analytical test device comprising a dry porous carrier (100), such as nitrocellulose or polyethylene, with the ability to effect a chromatographic separation and with a pore size of about 10 to about 50 microns, encased in a housing (comprising 120 and 140) having a well (132) which provides a means for applying a liquid samples, such as urine, to the dry porous carrier indirectly, i.e. through a pad or macroporous body (110) which is different from and adjacent to the dry porous carrier (100). See column 10, line 50 through column 11, line 28. The dry porous carrier contains at least one indicator or detection zone comprising

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immobilized unlabelled specific binding partner for target analyte along with optional control and reference zones. See column 7, lines 19-30. The macroporous pad contains diffusible specific binding partner conjugated to a conventional label, e.g. a colored latex particle. See column 5, lines 28-36. The device's housing further comprises apertures (146a and 146b) for viewing the various detection, control and/or reference zones. See column 12, lines 21-36. Suitable analytes include those conventionally measured by standard sandwich or competitive immunoassays, including hormones, such as hCG, using conventional sample types, such as blood and urine. See also figures 1 and 2.

Eisinger differs from the instant invention in failing to specifically teach that disc 110 (the macroporous body) contains particulate direct labels. However, Eisinger does teach that the pad/disc 110 may, in an ELIZA, contain enzyme-labeled antibody. Eisinger also teaches that the device, in general, may be used in assays with different configuration using different reagents, one of which is a particulate, direct label. Therefore, it is clearly obvious to one of ordinary skill in the art that when particles, such as latex, are chosen as the label instead of an enzyme, that such labeled binding partner also resides in disc 110.

#### *Claim Rejections - 35 USC § 103*

5. Claims 28, 31, 37, 38, 47, 50, 56, 57, 64-83, 90, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisinger in view of May et al (EPA 0,291,194) and, if necessary, Olsen (US 4,963,468).

See the discussion of Eisinger above. Eisinger differs from the claimed invention in failing to teach latex particles having a maximum dimension under 0.5 microns; latex colored with a fluorescent dye; macroporous pad pore size at least 10 times greater than the average

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size of the particulate label; a porous receiving member producing out the housing, which receiving member is covered with a removable cap; and adaptation of the device for LH analysis.

May, however, disclose a housed immunoassay device, similar in internal design in function and materials to that disclosed by Eisinger, which provides a protruding porous receiving member covered by a removable cap for applying liquid test sample, such as urine, to the test device within the housing. May discloses colored latex particles having a maximum diameter from about 0.05 to about 0.5 micron for use with a nitrocellulose carrier material of at least one to about 20 microns. The latex particles may be directly visible to the naked eye, or with the aid of applied stimulation, e.g. UV light to cause fluorescence. Adaptation of the test device for measurement of LH and hCG are disclosed as important alternative in fertility determination. See abstract; page 3, lines 13-20, 21, 35-47, 58; page 4, lines 1-16, 31, 42-46, page 5, lines 43-45 and page 6, lines 3-5. May also discloses a device incorporating two more discrete bodies of porous solid phase material, each carrying mobile and immobile reagents. These discrete bodies can be arranged in parallel such that a single application of liquid sample to the device initiates sample flow in the discrete bodies simultaneously (page 12, lines 6-20).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify the device of Eisinger by using conventional sized (fluorescently or visually) colored latex particles with preferred nitrocellulose immuno chromatographic porous carriers in a housed test device which housing comprises a protruding porous receiving member for applying liquid sample thereto as suggested by May for the same known and intended purpose of measuring immunoassay reactions using preferred materials and sample techniques as stated above. It would have been further obvious to adapt the instant device to

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such known and conventional analytes such hCG and LH which not only have important clinical significance in fertility testing but also are known to be successfully measured by analogous testing devices as suggested by both Eisinger and May. It also would have been obvious to adapt the instant device to incorporate two more porous carriers for detecting two or more analytes for the advantages cited in May above.

As to the macroporous pad pore size being at least 10 times greater than the maximum particle size of a selected particulate label, it would have been obvious to one of ordinary skill in the art to selected a pore size which provided optimum flow rate and permitted solubilization and migration of such particulate labels. Olsen, if necessary, discloses that one of ordinary skill in the art would have been motivated to use a macroporous pad with such a larger pore size so as to prevent the particulate immunoreagent from becoming embedded or non-diffusively bound in the macroporous pad. See column 15, lines 36-45.

#### *Response to Arguments*

6. Applicant's arguments with respect to claims 26, 27, 29, 30, 32-36, 39-46, 48, 49, 51-55, 58-63, 84-86, 89, 91, 92 and 95 have been considered but are moot in view of the new ground(s) of rejection.

#### *Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. – 5:00 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'B. Nguyen', with a long horizontal flourish extending to the right.

Bao-Thuy Nguyen

Primary Examiner

23 July 2003